REMARKS

I. Claim Rejections under 35 U.S.C. §112

Claims 1-9, 14-15, and 16-25 were rejected as failing to comply with the written description requirement in that certain terminology was deemed to be new matter. The phrases that formed the basis for the rejection in the claims have been deleted.

II. Claim Rejections under 35 U.S.C. §101

Claims 1-15 and 26 were rejected as being directed to non-statutory subject matter because the claims allegedly recite only abstract ideas and were without practical application. As noted in the office action, the requirement of a practical application is satisfied if a useful, concrete and tangible result is produced. The method claims have been amended to recite a step of applying MRI electromagnetic radiation bursts to the patient synchronized with operational conditions of the IMD based upon the timing information received, whereby tissue being imaged is placed in a substantially common state during each burst. This step sets forth a useful, concrete and tangible result that is produced by practice of the claimed method, which satisfies the requirement for statutory subject matter.

III. Claim Rejections under 35 U.S.C. §102

Claims 1, 4, 8-10, 14-16, 22, 23, and 26 stand rejected as allegedly anticipated by the '328 patent to Foster et al. (Foster) under 35 U.S.C. §102(b). Applicants respectfully traverse the rejections.

Foster discloses two different devices provided with electromagnetic interference (EMI) resistance such as encountered during an MRI. The first device is an implantable cardiac assist device having two pacing modules. The first module is activated in the absence of EMI and is the primary pacing control. The second module is activated in the presence of EMI when the first module deactivates. The second module provides backup pacing in a VOO mode (i.e., no sensing and thus no triggered or inhibited response). See col. 4, lines 10-22.

The second device, which is shown in Fig. 5, is an external cardiac assist device having a resonant circuit interconnected between the device pacing circuit and the leads attached to a patient's heart. The resonant circuit is identified in Fig. 5 by reference numeral 448. When resonant circuit 448 is functional due to a discharge of an electromagnetic burst by the MRI, an open circuit is established that uncouples the pacing circuit from the pacing leads. This inhibits the flow of MRI-induced currents to the pacing circuit or via the leads to the patient's heart. See col. 10, lines 26-52:

> As is known to those skilled in the art, parallel-resonant circuits have very high impedances at or near the resonant frequency of the circuit and essentially perform as open switches at such resonant frequencies. When the parallel resonant circuit becomes functional (see step 448), it then prevents current at or near the resonant frequency from passing through it. **Thus, when this parallel-resonant circuit is interconnected between a cardiac assist device circuit and cardiac leads and is functional, it will effectively open the circuitry of the cardiac assist device, totally inhibiting current induced by the radio frequency fields of the MRI system from flowing to the device or via the leads to the heart** (see step 450). Therefore, the functional resonant circuit prevents the occurrence of deleterious effects on the cardiac assist device and the heating of the electrodes placed in the cardiac tissue. Thus, in the device of this application, the parallel resonant circuit which is activated provides means for ceasing the furnishing of electrical impulses from a cardiac assist device to a patient's heart; when alternating currents are supplied which deviate from frequency at which resonance occurs in the parallel resonant circuit, current is allowed to flow to the device, the amount of flow depending upon the deviation from the resonant frequency. Consequently, when the parallel circuit is not activated (at frequencies more or less than the resonant frequency), it acts as a closed switch, and there is provided means for furnishing the electrical impulses to the heart. (emphasis added)

Clearly, Foster fails to anticipate the claimed subject matter. First, the second device of Foster shown in Fig. 5 and relied upon does not disclose an implantable medical device having a telemetry unit that communicates timing information as to operational conditions of the IMD. Second, it necessarily follows that Foster does not disclose receiving information from an IMD as to its operational timing. The Foster device and methodology of Fig. 5 is merely a switching of the pacing "on and off" depending upon the presence of an MRI burst.

The anticipation rejection premised on Foster is clearly erroneous and should be withdrawn.

Claims 6 and 19-21 stand rejected as allegedly anticipated by the '906 patent to Terry et al. (Terry) under 35 U.S. C. §102(e). Applicants respectfully traverse the rejections.

Terry discloses a device similar to the first device described in Foster. That is, the magnetic field detector 370 in Fig. 3 upon detection of an MRI burst instructs the CPU to enter into the safe mode of operation. See col. 5, line 53 to col. 6, line 4. The safe mode includes reducing power, turning off amplifiers, or providing a predetermined lower pacing rate. See col. 9, lines 46-65.

Terry makes no disclosure whatsoever of any sort of synchronization between the timed operating conditions of an IMD communicated by the IMD and the application of MRI bursts. The characterization of Terry given in pages 8 and 9 of the office action is completely without basis.

The anticipation rejection premised on Terry is clearly erroneous and should be withdrawn.

IV. Claims Rejections under 35 U.S.C. §103

Claims 2, 3, 7, 11-13, 17, 18, 24, and 25 stand rejected as allegedly unpatentable over Foster in view of the '901 published application of Greatbatch (GB) under 35 U.S. C. §103(a). Applicants respectfully traverse the rejections.

The basis for the rejection is the erroneous contention that Foster teaches all the limitations of the independent claims except for specific mention of an MRI system. Foster clearly does mention an MRI system. However, more fundamentally, as set forth above in detail, Foster does not disclose the limitations of the independent claims. Thus, the proposed combination fails as a matter of law to reach the basic required threshold of providing a *prima facie* case of obviousness, and the rejection must be withdrawn.

V. Conclusion

The present invention is directed to an improved technique for MRI wherein the application of electromagnetic bursts is coordinated with the establishment of tissue being imaged in a substantially common state during each burst. Such coordination is provided by synchronizing the application of bursts in timed relationship to operating conditions of an IMD. Through such coordination, the accuracy of the MRI is improved and more effective imaging is realized.

The prior art of Foster teaches to uncouple the pulse generator from the patient, which prevents the pulse generator from having any effect whatsoever on the state of the tissue being imaged by the MRI device. Similarly, Terry teaches to modify the operation of the IMD, which renders it incapable of placing the tissue being imaged in a common state in synchronization with the application of electromagnetic bursts during a sequence of MRI imaging operations.

In view of the foregoing, it is believed that the application is now in condition for allowance and Applicants respectfully request the Examiner to issue a Notice of Allowance in due course so the instant invention can pass to timely issuance. The Examiner is invited to contact the undersigned with any questions regarding this application.

Respectfully submitted,

Date: January 8, 2007

/Paul H. McDowall/

Paul H. McDowall
Registration No. 34,873
Medtronic, Inc.
Telephone: (763) 514-3351
Facsimile: (763) 514-6982
Customer No. 27581